ECM certification

Application guide with additional explanations

Sectoral Accreditation Scheme

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Sectoral accreditation scheme

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A. Preliminaries

This document contains guidelines to be used by national accreditation bodies when assessing certification bodies performing ECM certification in conformity with the ECM Regulation.

Additional comments explaining this application guide further are presented in blue throughout the document.

B. Guidelines

1. INTRODUCTION

This document aims at providing to the National Accreditation Bodies the necessary common rules to accredit Certification Bodies who will deliver the certification of the entities in charge of Maintenance (ECM certification) against the specified requirements of the Commission Regulation *445/2011 of 10/05/2011 on a system of certification of the entity in charge of maintenance for freight wagons and amending Regulation (EC) No 653/2007* (ECM regulation).

The Sectoral (ECM) Accreditation scheme shall be compliant with the Regulation n° 765/2008 of the European Parliament and of the Council of 9 July 2008 *setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93.*

2. REFERENCE DOCUMENTS AND DEFINITIONS

2.1. Reference documents

2.1.1. Legal texts

1) 'Safety Directive' means the *Directive 2004/49/EC OF the European Parliament and of the Council of 29 April 2004 on safety on the Community's railways and amending Council Directive 95/18/EC on the licensing of railway undertakings and Directive 2001/14/EC on the allocation of railway infrastructure capacity and the levying of charges for the use of railway infrastructure and safety certification and all amendments*.
   Note: It includes of course all the amendments published until the date of this document.

2) 'ECM regulation' means the *Regulation 445/2011 of 10/05/2011 on a system of certification of entities in charge of maintenance for freight wagons and amending Regulation (EC) No 653/2007* (ECM regulation).
   Note: It includes of course all the amendments published until the date of this document.

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3) *Regulation n° 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93*.

   Note: It includes of course all the amendments published until the date of this document.

2.1.2. Other reference documents

1) **EN 45011:1998** General requirements for bodies operating product certification systems (ISO/IEC Guide 65:1996)

2) **EN ISO/IEC 17021:2011** Conformity assessment -- Requirements for bodies providing audit and certification of management systems

3) **ISO/IEC 17007:2009** Conformity assessment -- Guidance for drafting normative documents suitable for use for conformity assessment

4) **EA 2/11**: EA Policy, Criteria and Procedure for the Evaluation and Recognition of sectoral Conformity Assessment Schemes for inclusion in the EA MLA

5) Application guide :**ECM certification scheme** (version 1.0 of 21/10/2011)

6) Application guide: **Maintenance Workshop certification scheme** (version 1.0 of 21/10/2011)

Specific certification schemes addressing other separate maintenance functions than maintenance workshops certification will be provided by ERA in 2012.
They shall in any case apply the principles stated in article 8 and annex I of the ECM Regulation, which can be used by national accreditation bodies for the certification of separate maintenance functions before these specific schemes are available.

2.2. Definitions

The definitions of the Safety Directive and the ECM Regulation are applicable.
The definitions of ISO 9000:2005 are applicable.

To ensure a good and clear understanding of this document, the following definitions are repeated here:

(a) Accreditation

means accreditation as defined in Article 2(10) of Regulation (EC) No 765/2008 of the European Parliament and of the Council

(b) Certification committee

means the Committee established by the certification body for delivering an opinion on which the certification decision is taken by the certification body.
(ECM certification scheme-Maintenance workshop certification scheme)

(c) Certification decision

Granting, continuing, expanding the scope of, and reducing the scope of, suspending, restoring, withdrawing or refusing certification.

NOTE A certification scheme can utilize some or all of these types of certification decisions.

(ISO)

(d) Certification scheme

According to ISO, certification scheme means certification system related to specified products, to which the same specified requirements, specific rules and procedures apply. According to EN 45011:1998, products must be understood as manufactured products, services or processes.

(e) Certification scheme owner

Individual or organisation which is responsible for developing and maintaining a certification scheme.

NOTE 1 The certification scheme owner can be the certification body itself, a governmental authority or other.
(ISO)

NOTE 2 For accreditation, the scheme owner is ERA

(f) Certification system

Rules, procedures, and management for carrying out certification.
(ISO)

(g) Conformity assessment system
Rules, procedures and management for carrying out conformity assessment

NOTE Conformity assessment systems may be operated at international, regional, national or sub-national level.
(ISO)

(h) Conformity assessment scheme - Conformity assessment programme
Conformity assessment system related to specified objects of conformity assessment, to which the same specified requirements, specific rules and procedures apply
(ISO)

(i) European Co-operation for accreditation (EA)
means the European association of national accreditation bodies recognised against the European Regulation 765/2008. All Member states of the European Union are members of EA.
(www.european-accreditation.org)

(j) EA Multi-Lateral Agreement (EA MLA)
means the agreement signed between the EA accreditation body members to recognise the equivalence, reliability and therefore acceptance of accredited certifications, inspections, calibration certificates and test reports across Europe.

(k) Entity in charge of maintenance (ECM)
means an entity in charge of maintenance of a vehicle, and registered as such in the national vehicle register.
(ECM regulation)

(k) European Identification Number
Means the number for which the structure is ruled by Appendix 2 of COMMISSION DECISION 2007/756 (EC) *of 9 November 2007 adopting a common specification of the national vehicle register provided for under Articles 14(4) and (5) of Directives 96/48/EC and 2001/16/EC* (including amendments)

(l) European Railway Agency (ERA)
means the European Institution providing the EU Member States and the Commission with technical assistance in the fields of railway safety and interoperability.
ERA is established and ruled by the Regulation (EC) No 881/2004 *of the European Parliament and of the Council of 29 April 2004 establishing a European Railway Agency* (including all amendments)

(m) Freight wagon
means a non-self-propelled vehicle designed for the purpose of transporting freight or other materials to be used for activities such as construction or infrastructure maintenance
(ECM regulation)

(n) Maintenance workshop

means a mobile or fixed entity composed of staff, including those with management responsibility, tools and facilities organised to deliver maintenance on vehicles, parts, components or sub-assemblies of vehicles
(ECM regulation).

(o) N**ational safety authority** (NSA)
means a safety authority as defined in Article 3(g) of Directive 2004/49/EC;

(p) Process
Set of interrelated or interacting activities which transforms inputs into outputs.
(ISO)

(q) Product
Result of a process.

NOTE 1 Four generic product categories are noted in ISO 9000:2005: services (e.g. transport); software (e.g. computer program, dictionary); hardware (e.g. engine, mechanical part); processed materials (e.g. lubricant).

Many products comprise elements belonging to different generic product categories. Whether the product is then called service, software, hardware or processed material depends on the dominant element.

NOTE 2 Products include results of natural processes such as growth of plants and formation of other natural resources.

(ISO)

(r) Separate maintenance function
refers to entities performing limited scope of maintenance activities as considered in the ECM Regulation (in particular article 8 and annex I)

2.3. Abbreviations

CSM	Common Safety Methods
EA	European Co-Operation for Accreditation
EA (MLA)	EA Multi-Lateral Agreement
ECM	Entity in Charge of Maintenance
EN	European Norm
ERA	European Railway Agency (scheme owner)
GCU	General Contract of Use
IAF	International Accreditation Forum
(IAF) MD	Mandatory document of IAF
IM	Infrastructure Manager
ISA	Independent Safety Assessment Body
ISO	International Organization for standardization
NDT	Non-Destructive Test
NVR	National vehicle Register
OTIF	Intergovernmental Organisation for International Carriage by Rail

RID	Regulation concerning the International Carriage of Dangerous Goods by Rail
RU	Railway undertaking

3. SECTORAL ACCREDITATION SCHEME

The European Railway Agency (ERA) is the scheme owner in consistency with the rules of EA.

The scheme owner is the entity who requests for sectoral accreditation scheme against the EA rules.
According to the article 13(2a.) of regulation n° 765/2008, the European Commission should be the scheme owner.
In relation to the ECM regulation, ERA proposes to be the scheme owner on behalf of the European Commission.

As stated in article 13(2a), ERA shall address scheme proposals to the EU Commission (DG MOVE) for presentation to relevant Committees (at least RISC- Railway Interoperability and Safety Committee).

This section considers:

- The objectives of the accreditation
- The scope of the accreditation
- The requirements for accreditation

3.1. Objectives of the accreditation

The accreditation aims at ensuring the competence of certification bodies to perform certification activities[1] stated in the ECM Regulation. Competence of certification bodies is not limited to technical competence but includes also non-technical competence and other elements stated in annex II of the ECM Regulation, necessary to perform the assessment and delivery of certification stated in the ECM Regulation and in the ECM certification scheme.

The technical competence is related to the railway technical domain relevant to the maintenance of freight wagons.
The non-technical competence is related to the certification aspects such as methods to organise and conduct assessments including audits and inspections.
The other elements stated in annex II of the ECM Regulation are independence, impartiality, responsibility, openness, confidentiality, responsiveness to complaints and aspects linked to documented organisation, liability and financing.

The accreditation aims also at supporting the equivalence between certificates delivered according to the ECM regulation.

This ECM accreditation scheme shall be applied in all countries where the EA MLA is in force.

[1] *It includes the certification of ECM, maintenance workshops and separate maintenance functions delivered in conformity with the ECM Regulation.*

According to EA rules, a sectoral accreditation scheme validated by EA shall be applied in all countries who signed the EA MLA. For ECM certification against the ECM Regulation, the sectoral accreditation scheme is called '*ECM accreditation scheme'*

3.2. Scope of the accreditation

The accreditation addresses the two kinds of certification defined in the ECM Regulation:

- the certification of Entity in Charge of Maintenance; and
- the certification of Separate Maintenance Function including the certification of Maintenance Workshop

These two kinds of certification are described in detailed manner in the ECM certification scheme (version 1.0 of 28/10/2011).and in the maintenance workshop certification scheme (version 1.0 of 28/10/2011).

The certification body may choose to be accredited for one or several kinds of certification.
The accreditation related to the certification of Entity in Charge of Maintenance covers automatically the certification of separate maintenance functions.

1) The ECM maintenance system contains the four functions described in the article 4 of the ECM regulation.
The ECM internal maintenance functions, - i.e. maintenance development, fleet maintenance management and maintenance delivery-, may perform activities only for their own ECM or may also provide services to other ECMs

For providers of separate maintenance functions, it is reasonable to consider that they intend to provide services to several ECMs**.**

The certification bodies have to take into account, within their assessments, this additional complexity of providing services to several entities leading to additional risks for safety. Additional risks are related to multiplication of different channels for exchanging information and to the coverage of various different customers' requirements.
Nevertheless the certification processes remain similar in all cases.

To conclude, the applicant has to define with precision for which scope of activities he wants to be certified against the ECM Regulation. The certification body has to take care to this requested scope.

Consequently the national accreditation body has also to integrate the complexity mentioned here above in its assessment of the certification body. But the assessment processes implemented by the accreditation body remain similar in all cases.

Therefore it is reasonable to consider that a certification body accredited to deliver certifications to ECMs is also capable to take care of the complexity related to certifications of separate maintenance functions.

2) Separate maintenance functions include also the management function applied to the scope of activities of the applicant in conformity with article 8 and annex I of the ECM Regulation.

3.3. Requirements for accreditation

Having considered the ECM regulation and the ECM certification scheme, the certification body shall be accredited against EN 45011:1998 with the following specific requirements:

1) a) For the certification of Entity in Charge of Maintenance, the certification process shall be compliant with the ECM certification scheme (version 1.0 of 28/10/2011). Therefore the certification process is also compliant with section 9 of ISO 17021:2011.

   b) For the certification of Separate Maintenance Functions including the certification of maintenance workshop, the certification process shall be compliant with the applicable sections of the ECM certification scheme (version 1.0 of 28/10/2011) and the Maintenance workshop certification scheme (version 1.0 of 28/10/2011). Therefore the certification process is also compliant with section 9 of ISO 17021:2011.

2) The section 7 of ISO 17021:2011 related to requirements addressing the competences of persons shall be applied with the specific competences requirements in section 3.4 of this document.

3.4. Specific competences requirements for persons

These specific requirements address the persons involved in the activities of assessment (assessment team) and delivery of the certificates (Certification Committee).

3.4.1. Assessment team

1) Base training and professional experience

Each member of the assessment team shall comply with the following requirements related to base training and professional experience:

- Professional experience minimum 9 years; or
- Secondary school degree in mechanical and professional experience minimum 7 years; or
- Bachelor[2] degree in engineering and professional experience minimum 5 years; or
- Master[3] degree in engineering, sciences or business management and professional experience minimum 3 years

The professional experience required shall be at least 3 years in positions related to:

- maintenance of railway freight wagons or (other) railway vehicles in maintenance development, fleet maintenance management or maintenance delivery; or
- design and manufacturing of railway vehicles; or

[2] *Bologna process terminology*
[3] *Bologna process terminology*

In the TSI approach, railway vehicles are composed of structural subsystems including rolling stock subsystem.

- assessment of maintenance system, staff or processes in other sectors such as automotive, civil aviation, energy, building technical equipments, industrial mechanical equipments, …; or
- assessment or management of welding activities or non-destructive tests activities;

At least one member of the assessment team has a strong proven professional experience of 3 years in maintenance of railway vehicles (management and engineering) among which 2 years in maintenance of freight wagons are required

At least one member of the assessment team has a strong proven professional experience in risk management.

The implementation of Regulation 352/2009 is a key aspect for creating, developing and maintaining trust in the capability of ECMs to assure safety through a maintenance system. The ECM certification scheme contains assessment of the compliance of ECM maintenance system with the Regulation 352/2009. Therefore it is crucial that the assessment team may rely on at least one member who has a professional experience in risk management.

This member may be the same than the one mentioned above with strong proven experience in maintenance of railway vehicles.

When required, the remaining period of professional experience should be in positions related to:

- design and manufacturing of railway vehicles; or

  In the TSI approach, railway vehicles are composed of structural subsystems including rolling stock subsystem.

- design, manufacturing or maintenance in automotive industry; or
- design, manufacturing or maintenance in civil aviation; or
- design, manufacturing or maintenance in steel industry (industrial equipments); or
- design, manufacturing or maintenance of energy production plant; or
- design, manufacturing or maintenance of technical equipments in building sector; or
- design, manufacturing or maintenance in other mechanical industry

2) <u>Complementary training, skills and knowledge</u>

It is not required that each member of the assessment team has got complementary training, skills and knowledge in all domains mentioned here below but the composition of the assessment team shall be well balanced to assure its competence for performing assessment and delivery of relevant assessment reports as stated in the ECM certification scheme.

The members of the assessment team shall have also got complementary training, skills and knowledge in following domains:

- European railway legal system including safety and interoperability aspects.
- Assessment and certification of management systems as ruled by international standards or industry standards relevant to railway.

  Industry standard such as IRIS.

- Inspections as ruled by international standards
- Applicable railway legislation, including:
  - CSMs compliant with art 6 of the Railway Safety Directive 2004/49;
  - technical specifications for interoperability according to the Railway Interoperability Directive 2008/57;
  - European legislation applicable to transport of dangerous goods (for instance RID); and
  - associated normative documents
- Applicable documents which are used in the framework of the Railway Safety and interoperability Directive (for instance, ERA publications, application guides, guidelines)
- ECM activities:
  - Existing rules and relevant documents specific for assessing ECMs (Regulation, certification scheme, guidelines,…)
  - Transitional measures such as certification against the MoU *establishing the basic principles of a common system of certification of entities in charge of maintenance for freight wagons of 14 May 2009* and industry's self declaration framework.
- Guides, recommendations and main maintenance plans which may be used as reference in order to set up an ECM maintenance file
  (for instance: VPI recommendation, NSA publications, former RU maintenance plan when RU acted as registering entity imposing maintenance, railway vehicles EN standards).
- Welding rules and good practises, particularly standard EN 15085, or equivalent, such as EN 287,
- Non Destructive Tests rules and good practises, including standard EN 473 or equivalent
- Braking system: technology, design rules and maintenance including international or industry standards
- Wheelset, running gear and draw gear technology, design rules and maintenance including international or industry standards

In case the certification body cannot assure that all the complementary skills, training and knowledge are met by the assessment team, it shall identify the necessary support activities to assure that the assessment team is competent. To achieve this, the certification body shall have procedures.

All the additional skills and knowledge required may lead to set-up an assessment team composed of too many members. This could impair the economic sustainability of the ECM certification.
Therefore the certification body has two choices:

- the assessment team is composed of sufficiently skilled members; skills and knowledge covering the list here above; or

- the certification body provides the necessary support to the assessment team to mitigate insufficient skills of members of assessment team during assessment.

In both cases, the certification body has to have documented procedures.

3) Language skills

Each member of the assessment team shall have the necessary language skills in consistency with the ECM certification scheme. B2 level[4] is required. It is not required that each member of the assessment team has B2 level for all languages agreed for the assessment but at least in one.
The composition of the assessment team shall be well balanced to assure its competence in all languages agreed for the assessment.

B2 is described in the European classification related to language skills developed by the European Institutions.
This B2 level may be assessed by a third party. For instance the European Commission qualifies assessment centres for assessing and delivering languages certificates in conformity with the European classification.

The B2 level may be directly evaluated by the certification body against documented procedures.

3.4.2. Certification Committee

At least one member of the Certification Committee has a strong proven experience in management and/or product certification preferably in industrial sectors.

At least one member of the Certification Committee has a strong proven professional experience of 7 years in maintenance of railway vehicles (management or engineering) among which 5 years in maintenance of freight wagons are required.

For each submitted dossier, the members of the Certification Committee have sufficient language skills to understand all assessment reports. B2 level[5] in reading skill is required.

4. Identification

The Accreditation Body shall identify each decision on accreditation, i.e. delivery, revocation or suspension, in conformity with the European Identification Number (EIN)

The EIN structure is ruled by Appendix 2 of COMMISSION DECISION of 9 November 2007adopting a common specification of the national vehicle register provided for under Articles 14(4) and (5) of Directives 96/48/EC and 2001/16/EC (including amendments)

Structure of EIN

[4] *B2 level according to the European classification.*
[5] *B2 level according to the European classification.*

The EIN is structured as **XY/ab/cdef/ghij** where

The identification of the certificate includes the identification of the certification body.

The decision on accreditation will be identified by an EIN and delivered by the accreditation body.

'**XY**' = Country Code of the accreditation body.

'**ab**'= '30'

'**cd**' = counter that identifies the accredited body. From '01' to '99'
'**ef**' = year when the decision on accreditation is taken by the accreditation body (delivery, revocation, suspension). Example 2011: 'ef' ='11'

'**ghij**'= counter (4 digits). From '0001' to '9999'

Example:

FR/30/0211/0001: Accreditation decision '0001' taken in '2011' by the French Accreditation body (COFRAC) related to the certification body '02'.

The identification of ECM certificates and separate functions certificates is, notwithstanding the changes in this section, compliant with the provisions of appendix 2 of annex to the COMMISSION DECISION 756/2007 of 9 November 2007 *adopting a common specification of the national vehicle register provided for under Articles 14(4) and (5) of Directives 96/48/EC and 2001/16/EC* (OJ L305/44 of 23/11/2007 (including amendments published until the date of this document.)